# EXHIBIT 12

ORIGINAL

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION



IN THE MATTER OF A GRAND JURY INVESTIGATION OF USP LABS, LLC AND OTHERS

Case No. 3:14-MC-146-D

**FILED *EX PARTE* AND UNDER SEAL**

**APPLICATION FOR AN ORDER PURSUANT TO 18 U.S.C. § 3292 TO SUSPEND THE LIMITATIONS PERIOD**

The government files this *ex parte* application respectfully seeking an order from this Court suspending the statute of limitations for offenses being investigated by a grand jury of this district. As described herein, evidence of those offenses is located in the People's Republic of China ("China"), and the United States has made an official request to China to obtain this evidence pursuant to the multi-lateral assistance agreement ("MLAA") between the two countries.

## BACKGROUND OF THE INVESTIGATION

### 1. Jack3d and OxyElite Pro

USP Labs is a dietary supplement company whose principals are Jacob Geissler, Jonathan Doyle, and Matthew Hebert. Declaration of Special Agent Chad Medaris (Dec. 9, 2014) ¶ 6 (Ex. 1). In or about late 2008, USP Labs began widely distributing a product called "Jack3d," which was aimed at the bodybuilding community. Medaris Decl. ¶ 8. Jack3d was a "pre-workout" supplement. Medaris Decl. ¶8. USP Labs claimed that the product would increase the overall impact of workouts by causing a "thermogenic" effect that would burn fat and create muscle. *Id.* In or about late 2009, USP Labs began distributing a similar product

called "OxyElite Pro," which was aimed at a more general audience as a weight management product. *Id.* ¶ 9.

In their first formulations, OxyElite Pro and Jack3d contained an amphetamine-like stimulant called 1,3-dimethylamylamine ("DMAA") that was a new, synthetic ingredient in dietary supplements. *Id.* ¶ 11. USP Labs obtained much of its DMAA from SmartChem (Beijing) Ltd. ("SmartChem") in Beijing, China. *See* Email from Raphael to Patel (Sept. 28, 2010) (email and attachments reflecting 1,000 kg shipment of DMAA from SmartChem) (Ex. 2). USP Labs was introduced to this substance by Sitesh Patel, who is one of the principals of SK Laboratories ("SK Labs") in Southern California, a firm that performed most of the manufacturing of USP Labs' products. Deposition of Jacob Geissler (July 27, 2014) at 86, 88-91 (Ex. 3); Medaris Decl. ¶¶ 6, 10. Sitesh Patel also introduced Jacob Geissler to Vincent Zhou, SmartChem's Director of Export Operations. Email from Patel to Geissler (Oct. 13, 2008) (Ex. 4). USP Labs ordered thousands of kilograms of DMAA from SmartChem over the next four years. *See* Packing Lists (Ex. 5).

Despite knowing since at least 2009 that the DMAA it was purchasing from China was synthetically created, Email from Patel to Geissler (May 22, 2009) (Ex. 6), USP Labs and SK Labs caused Vincent Zhou to mislabel shipments from China to the United States to make it appear as if the substance was naturally extracted from the stems of the geranium plant, *see* Packing Lists (Ex. 5). USP Labs also caused Vincent Zhou to send certificates of analysis along with the DMAA shipments. *See* Certificates of Analysis (Ex. 7). The certificates of analysis falsely stated that the substance had been extracted from geranium plants. *Id.* Evidence suggests that the targets took these steps in order to avoid arousing suspicion from U.S. authorities, as well as to make the substance appear natural and more acceptable to dietary supplement retailers.

Email from Geissler to Zhou (Feb. 25, 2011) (instructing SmartChem to label a chemical shipment as "green coffee extract" in order to evade customs) (Ex. 8); Email from Patel to Doyle and Geissler (July 16, 2009) (discussing how the targets can have "China . . . doctor" a certificate of analysis to state that a synthetic substance is actually an extract because "GNC and retails might be more open if they see it's an extract") (Ex. 9). USP Labs also mislabeled its products to reflect the idea that the DMAA it was using came from geranium stems, *see* Jack3d Label (Ex. 10), and made similar misrepresentations to retailers in the United States when those retailers refused to sell synthetic DMAA, *see* Email from Hebert to Geissler and McKeon (May 14, 2010) (Ex. 11).

OxyElite Pro and Jack3d quickly became two of the most popular workout supplements on the market in the United States, sold nationwide in large retail chains, through many other locations and Internet sites. Medaris Decl. ¶11. But with OxyElite Pro and Jack3d's widespread availability and use came numerous reports of adverse health events linked to products containing DMAA. For example, a U.S. Department of Defense report concluded that U.S. service members taking DMAA supplements were 3.5 times more likely to experience an adverse medical event than service members who did not use a supplement containing DMAA. *See* Report of the Department of Defense 1,3 Dimethylamylamine (DMAA) Safety Report Panel (June 3, 2013) at 9 (Ex. 12). There were also numerous anecdotal accounts of DMAA-related injuries. For example, in April 2012, a runner in the United Kingdom died while competing in a marathon race, and an official inquiry found that DMAA was a factor in her death. *See* BBC News, "Clair Squires inquest: DMAA was factor in marathon runner's death." (Jan. 30, 2013) (Ex. 13).

In April 2012, the U.S. Food and Drug Administration ("FDA") sent a letter to USP Labs, advising the company that its use of DMAA in dietary supplements was and had been illegal under the Federal Food, Drug, and Cosmetic Act because, among other reasons, it did not appear that DMAA was naturally occurring and, therefore, it could not qualify as a dietary ingredient. *See* Letter from Roosevelt to Geissler (April 24, 2012) (Ex. 14). Even if it could qualify as a "dietary ingredient," FDA told USP Labs that it was unaware of information establishing that DMAA did not pose an unreasonable risk of illness or injury. *Id.* Despite the warning letter, USP Labs continued selling OxyElite Pro and Jack3d in the United States, and sent letters to FDA indicating that it believed DMAA was not illegal for a variety of reasons not supported by the law or the facts. *See* Letter from Thomas to Doyle (April 18, 2013) (discussing and rejecting USP Labs' claim that DMAA is a "dietary ingredient") (Ex. 15). USP Labs maintained that position for a year, but in April 2013, USP Labs issued a press release announcing to the public that, while it disagreed with the FDA, it had "concluded for business reasons to phase-out products containing 1,3-DMAA and replace them with new advanced formulations." *See* USPLabs, Press Release (Apr. 16, 2013) (Ex. 16).

Although USP Labs made that announcement, it failed to initiate a recall of the large amount of its DMAA-containing product that was already in the stream of commerce. In June and July 2013, the FDA and the U.S. Department of Justice administratively detained and/or filed seizure actions against large amounts of OxyElite Pro and Jack3d contained in four warehouses. *E.g., United States v. 860 Cases of OxyElite Pro,* No. 13-cv-1675 (D.S.C. complaint filed June 19, 2013); *United States v. 547 Cases of OxyElite Pro*, No. 13-cv-1246 (D. Ariz. Complaint filed June 21, 2013). In summer 2013, USP Labs and General Nutrition Corporation, USP Labs' largest retailer of the DMAA-containing products, agreed to destroy the

DMAA-containing product stored in those locations. *See* FDA Voice, "Dietary Supplements Containing Unsafe Food Additive Destroyed" (July 30, 2013) (Ex. 17).

**2. USP Labs Reformulates OxyElite Pro to Include Harmful New Ingredients from SmartChem in China**

In contrast to the representations USP Labs made to the public and to the government about its apparently prospective decision to remove DMAA in April 2013, in fact, USP Labs had already reformulated OxyElite Pro months earlier—in November 2012—to remove DMAA and substitute a different, illegal, dietary ingredient in its place. Medaris Decl. ¶12. This new formulation of OxyElite Pro, called "OxyElite Pro Advanced" or "OxyElite New Formula," contained a new ingredient called aegeline. *Id.* USP Labs also produced a separate weight-loss product, VERSA-1, that also contained aegeline. *Id.*

Just as with DMAA, USP Labs' aegeline was supplied by Vincent Zhou and SmartChem in China. *See* Email from Doyle to Geissler and Houglund (July 20, 2012) (Ex. 18). Also known as N-[2-hydroxy-2(4-methoxyphenyl) ethyl]-3-phenyl-2-propenamide, aegeline is illegal under the Federal Food, Drug, and Cosmetic Act for the same reasons, among others, that DMAA is illegal. That is, assuming that the synthetic aegeline USP Labs used could qualify as a dietary ingredient at all, it would be a new dietary ingredient for which USP Labs failed to provide a new dietary ingredient notice to FDA. *See* Letter from Correll to Geissler (Oct. 11, 2013) (Ex. 19). In July 2013, USP Labs reformulated OxyElite Pro again to add, in addition to aegeline, another illegal ingredient called cynanchum auriculatum. Medaris Decl. ¶13. The cynanchum auriculatum that USP Labs used also came from Vincent Zhou and SmartChem in China. Email from Zhou to Wangler et al. (June 28, 2013) (Ex.20). When USP Labs added this ingredient, it knew that scientific studies had shown it could be potentially harmful and cause liver toxicity. *See* Email from "erik" to Geissler (July 13, 2013) (Ex. 21).

### 3. The Fall 2013 Outbreak of OxyElite-Induced Hepatic Injuries

In September 2013, the U.S. Centers for Disease Control and Prevention and FDA began tracking an outbreak of severe liver injuries that were linked to the use of OxyElite Pro and VERSA-1. *See* FDA, "OxyElite Pro Supplements Recalled" (Nov. 2013) (Ex. 22). Although many of the initial reports came from the State of Hawaii, subsequent investigation revealed reports from other states as well. *Id.* Among the users of OxyElite Pro and VERSA-1, there was a report of one patient death, there was a report of one patient death and several patients who received emergency liver transplants, as well as dozens of reports of other liver injuries. *Id.*

Among many other questionable actions USP Labs took in response to the outbreak, on October 8, 2013, the company told the public: "We know of no credible evidence linking OxyElite Pro to liver issues. The ingredients have been studied for safety, are consumed in the food supply and widely used in dietary supplements. The studies and consumption history show no negative liver issues." *See* USP Labs Press Release (Oct. 8, 2013) (Ex. 23). Next, after promising the FDA in early October that it would stop distributing OxyElite Pro, *See* Email from Miles to Rodriguez (Oct. 8, 2013) (Ex. 24), USP Labs distributed large volumes of OxyElite Pro to a large dietary supplement distributor in Panama. Medaris Decl. ¶14. FDA sent a warning letter related to the firm's use of aegeline on October 11, 2013, (Ex. 19), and USP Labs agreed in November 2013 to recall aegeline-containing products. *See* USP Labs Press Release (Nov. 9, 2013) (Ex. 25).

### 4. USP Labs' Extensive Dealings with Vincent Zhou of SmartChem

As discussed above, Vincent Zhou and SmartChem have provided very large amounts of substances for use in USP Labs' supplements in the United States. As part of those purchases, USP Labs transmitted large payments to SmartChem's bank account at Ping An Bank in China.

Evidence shows that USP Labs wired a total of over $16 million to SmartChem's bank account between May 2010 and August 2013, mostly in large monthly payments. *See* USP Labs Bank Statements (Ex. 26).

Moreover, USP Labs' dealings with Vincent Zhou and SmartChem go far beyond SmartChem's role as a broker and supplier. Rather, USP Labs frequently engaged Vincent Zhou and SmartChem to synthesize or attempt to synthesize other central nervous system stimulants, with the express goal of establishing markets in the United States that SmartChem and USP Labs intended to supply and from which they intended to derive profits. Email from Geissler to Zhou (July 2, 2010) (Ex. 27). As part of that conduct, USP Labs caused Vincent Zhou and SmartChem to mislabel shipments of prospective new ingredients as "green coffee extract," when in fact the shipments did not contain green coffee extract. Email from Zhou to Houglund and Geissler (Dec. 10. 2012) (sending three substances and labeling them as "green coffee extract") (Ex. 28); Email from Zhou to Geissler (Mar. 21, 2013) (sending three synthetic chemicals as "green coffee extract") (Ex. 29). With those shipments, Vincent Zhou also sent false invoices that did not reflect the true value of the substances sent, apparently in order to assist USP Labs in evading customs duties. *Id.* (reflecting Zhou's statements that a "true value" invoice would be sent by email in addition to a different invoice that was included with the shipment).

**5. The Request for Assistance to China**

On March 30, 2015, the deputy director of the Office of International Affairs in the Criminal Division of the United States Department of Justice prepared an official request for assistance to the Chinese government related to the conduct described above. *See* MLAA Cover

Letter and FedEx Receipt (Ex. 30); Declaration of Patrick Runkle (Ex. 31). The request was translated into Mandarin Chinese and was sent to Chinese authorities on April 2, 2015. Ex. 30.

## ARGUMENT

Pursuant to 18 U.S.C. § 3292, the statute of limitations for federal criminal offenses may be suspended by the Court:

> Upon application of the United States, filed before return of an indictment, indicating that evidence of an offense is in a foreign country, the district court before which a grand jury is impaneled to investigate the offense shall suspend the running of the statute of limitations for the offense if the court finds by a preponderance of the evidence that an official request has been made for such evidence and that it reasonably appears, or reasonably appeared at the time the request was made, that such evidence is, or was, in such foreign country.

18 U.S.C. § 3292(a).

Based on the plain language of the statute, therefore, what is required is for the government to file an application with the Court proving by a preponderance of the evidence that an "official request has been made" for foreign evidence of an offense being investigated by the grand jury, and that "it reasonably appears" that the evidence is in fact located in such foreign country. *Id.* Furthermore, the statute states that an application is to be "filed before the return of an indictment." *Id.*[1]

If these conditions are met, the Court "shall" suspend the limitations period, acting on the government's application in 30 days. *Id.* Tolling begins on the date of the official request to the foreign country—here, April 2, 2015—and ends after three years or "on the date on which the

[1] There is a split of authority on whether the government's application itself must come before the expiration of the statute of limitations on the prospective charges. *Compare United States v. Kozeny*, 541 F.3d 166 (2d Cir. 2008) (application to the court must come prior to the expiration of the statute of limitations) *with United States v. Miller*, 830 F.2d 1073 (9th Cir. 1987) (court may retroactively toll statute of limitations as long as application is filed prior to indictment). This Court need not take a position on the issue now because no charges have been filed and the statute of limitations can only be measured by the acts charged in an indictment.

foreign court or authority takes final action on the request," whichever is shorter. 18 U.S.C. § 3292(b), (c); *United States v. Meador*, 138 F.3d 986 (5th Cir. 1998).

1. **An Official Request Has Been Made for Evidence in the People's Republic of China, and No Indictment Has Been Returned in This Investigation**

Based on the official request that was sent to the People's Republic of China on April 2, 2015 (Ex. 30), and the attached Declaration of Patrick Runkle (Ex. 31)—which verifies that the request for assistance was transmitted to China—the United States has proven by a preponderance of the evidence that "an official request has been made" to Chinese authorities to obtain evidence. 18 U.S.C. § 3292(a).

Furthermore, this application is being filed prior to the return of an indictment as to any of the charges being investigated. *Id.* Two of the conditions specified in 18 U.S.C. § 3292(a) have therefore been satisfied.

2. **It Reasonably Appears That Evidence of the Offenses Being Investigated by the Grand Jury Is in the People's Republic of China**

Based on the Medaris Declaration and other supporting exhibits described in the factual background section above, it reasonably appears that evidence related to a wide variety of criminal offenses under investigation by the grand jury is located in China. Among other things, USP Labs engaged in a five-year course of dealing with SmartChem whereby SmartChem provided vast quantities of illegal substances for use in dietary supplements in the United States as well as potentially fraudulent documentation thereof. SmartChem was paid over $16 million for these activities.

Based upon evidence collected to date by the grand jury, it is reasonable to believe that relevant evidence is located in China which relates to all the potential offenses involving the substances that USP Labs obtained from China. For example, SmartChem's internal

documentation and communications about how it synthetically produced the substances at issue are relevant to the government's case. SmartChem's internal documents and communications reflecting how it procured the other purported natural and synthetic substances that it sent to the U.S. are also highly relevant. Additionally, it is unknown whether Vincent Zhou and SmartChem engaged in electronic communications with any of the U.S. targets that were either deleted by USP Labs' server prior to execution of the search warrant or were completed using some form of communication that were not seized by the government.

## CONCLUSION

Pursuant to 18 U.S.C. § 3292, the government respectfully requests that this Court suspend the running of the statute of limitations as it relates to offenses described herein. As per the statute, the tolling period begins on the date the request for evidence was sent to the foreign government—here, April 2, 2015. A proposed order is attached as Exhibit 32.

Dated: April 22, 2015

Respectfully Submitted,

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